

**PATIENT INFORMATION LEAFLET
DR. REDDY'S LABORATORIES (PTY) LTD.
SUGAMMADEX 200 AND 500 DRL
(SOLUTION OF INJECTION)**

SCHEDULING STATUS: S4

SUGAMMADEX 200 DRL, Solution for injection

SUGAMMADEX 500 DRL, Solution for injection

Sugammadex

Sugar free

This product contains 9,7 mg sodium

Read all of this leaflet carefully before you are given SUGAMMADEX DRL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What SUGAMMADEX DRL is and what it is used for
2. What you need to know before you use SUGAMMADEX DRL
3. How SUGAMMADEX DRL is given
4. Possible side effects
5. How to store SUGAMMADEX DRL
6. Contents of the pack and other information

1. What SUGAMMADEX DRL is and what it is used for

The active substance is sugammadex. SUGAMMADEX DRL is considered to be a *Selective Relaxant Binding* medicine that works with specific muscle relaxants, rocuronium bromide or vecuronium bromide. When you have some types of operations, your muscles must be completely relaxed. This makes it easier for the surgeon to do the operation. For this, the general anaesthetic you are given includes medicines to make your muscles relax. These are called *muscle relaxants*, and examples include rocuronium bromide and vecuronium bromide. Because these medicines also make your breathing muscles relax, you need help to breathe (artificial ventilation) during and after your operation until you can breathe on your own again. SUGAMMADEX DRL is used to speed up the recovery of your muscles after an operation to allow

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you to breathe on your own again earlier. It does this by combining with the rocuronium bromide or vecuronium bromide in your body. It can be used in adults whenever rocuronium bromide or vecuronium bromide is used and in children and adolescents (aged 7 to 17 years) when rocuronium bromide is used for a moderate level of relaxation.

2. What you need to know before you use SUGAMMADEX DRL

SUGAMMADEX DRL should not be administered to you

- if you are hypersensitive (allergic) to sugammadex, or any of the other ingredients of SUGAMMADEX DRL (listed in section 6).

Tell your health care provider if this applies to you.

Warnings and precautions

Talk to your health care provider before SUGAMMADEX DRL is given

- if you have kidney disease or had in the past. This is important as SUGAMMADEX DRL is removed from your body by the kidneys.
- if you have liver disease or have had it in the past.
- If you have cardiovascular (heart and blood vessel) disease.
- if you have fluid retention (oedema).
- if you have diseases which are known to give an increased risk of bleeding (disturbances of blood clotting) or anticoagulation medication.
- if you are on a controlled salt diet.

Children and adolescents

SUGAMMADEX DRL should not be administered to patients below 7 years of age.

Use in elderly

Elderly patients can be given the same dose as other adults, provided their kidneys are working well.

Other medicines and SUGAMMADEX DRL

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your health care provider if you are taking, have recently taken or might take any other medicines.

SUGAMMADEX DRL may affect other medicines or be affected by them.

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Some medicines reduce the effect of SUGAMMADEX DRL

It is especially important that you tell your health care provider if you have recently taken:

- toremifene (used to treat breast cancer).
- fusidic acid (an antibiotic).

SUGAMMADEX DRL can affect hormonal contraceptives

- SUGAMMADEX DRL can make hormonal contraceptives - including the 'Pill', vaginal ring, implants or a hormonal IntraUterine System (IUS) - less effective because it reduces how much you get of the progestogen hormone. The amount of progestogen lost by using SUGAMMADEX DRL is about the same as missing one oral contraceptive Pill.
 - If you are taking the **Pill** on the same day as SUGAMMADEX DRL is given to you, follow the instructions for a missed dose in the Pill's package leaflet.
 - If you are using **other** hormonal contraceptives (for example a vaginal ring, implant or IUS) you should use an additional non-hormonal contraceptive method (such as a condom) for the next 7 days and follow the advice in the package leaflet.

Effects on blood tests

In general, SUGAMMADEX DRL does not have an effect on laboratory tests. However, it may affect the results of a blood test for a hormone called progesterone and some blood clotting tests. Talk to your doctor if your progesterone levels need to be tested on the same day you receive SUGAMMADEX DRL.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your health care provider for advice before receiving this medicine.

Tell your health care provider if you are pregnant or might be pregnant or if you are breast-feeding.

The safe use of this medicine in pregnant women has not been established.

Driving and using machines

It is not always possible to predict to what extent SUGAMMADEX DRL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SUGAMMADEX DRL affects them.

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SUGAMMADEX DRL contains sodium

Tell your health care provider if you are on a controlled salt diet.

3. How SUGAMMADEX DRL is given

SUGAMMADEX DRL is given will be given to you by your health care provider, or under the care of your health care provider.

The dose

Your health care provider will work out the dose of SUGAMMADEX DRL you need based on:

- your weight
- how much the muscle relaxant medicine is still affecting you.

The usual dose is 2 to 4 mg per kg body weight. A dose of 16 mg/kg can be used in adults if urgent recovery from muscle relaxation is needed.

The dose of SUGAMMADEX DRL for children is 2 mg/kg (children and adolescents between 7 to 17 years old).

How SUGAMMADEX DRL is given

SUGAMMADEX DRL will be given to you by your health care provider. It is given as a single injection either directly into a vein or through an intravenous line.

If you receive more SUGAMMADEX DRL than you should

As your health care provider will be monitoring your condition carefully, it is unlikely that you will be given too much SUGAMMADEX DRL. But even if this happens, it is unlikely to cause any problems.

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

SUGAMMADEX DRL can have side effects.

Not all side effects reported for SUGAMMADEX DRL are included in this leaflet.

If these side effects occur while you are under anaesthesia, they will be seen and treated by your health care provider.

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Frequent side effects:

- Altered sense of taste.
- Cough.
- Airway difficulties that may include coughing or moving as if you are waking or taking a breath
- Light anaesthesia - you may start to come out of deep sleep, so need more anaesthesia. This might cause you to move or cough at the end of the operation.
- Complications during your procedure such as changes in heart rate, coughing or moving.
- Decreased blood pressure due to the surgical procedure.

Less frequent side effects:

- Shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems.
- Allergic (drug hypersensitivity) reactions - such as a rash, red skin, swelling of your tongue and/or throat, shortness of breath, changes in blood pressure or heart rate, sometimes resulting in a serious decrease of blood pressure. Severe allergic or allergic-like reactions can be life threatening.

Allergic reactions were reported more commonly in healthy, conscious volunteers .
- Return of muscle relaxation after the operation.

Frequency not known:

- Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when SUGAMMADEX DRL is administered.

If you notice any side effects not mentioned in this leaflet, please inform your health care provider.

Reporting of side effects

If you get side effects, talk to your health care provider. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of SUGAMMADEX DRL.

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5. How to store SUGAMMADEX DRL

Storage will be handled by healthcare professionals.

Unopened vial:

Store at or below 25 °C.

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

After reconstitution/dilution:

After first opening and dilution, store at 2 to 8 °C and use within 24 hours.

After first opening and dilution chemical and physical in-use stability has been demonstrated for 48 hours at 2 °C to 25 °C.

From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use

storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24

hours at 2 °C to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions

Discard any unused portion of the infusion solution.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What SUGAMMADEX DRL contains

- The active substance is sugammadex.
1 ml solution for injection contains sugammadex sodium equivalent to 100 mg sugammadex.
Each vial of 2 ml contains sugammadex sodium equivalent to 200 mg sugammadex.
Each vial of 5 ml contains sugammadex sodium equivalent to 500 mg sugammadex.
- The other ingredients are water for injections, hydrochloric acid, sodium hydroxide and water for

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injections.

What SUGAMMADEX DRL looks like and contents of the pack

SUGAMMADEX 200 DRL is packed in 2 ml tubular, Type-I glass vials with a 13 mm neck finish, sealed with 13 mm grey, teflon-coated rubber stoppers firmly sealed with flip-off seals.

SUGAMMADEX 500 DRL is packed in 5 ml tubular, Type-I glass vials with a 20 mm neck finish, sealed with 20 mm grey, teflon-coated rubber stoppers firmly sealed with flip-off seals.

The rubber stoppers do not contain latex.

Pack sizes: 1 or 10 vials of 2 ml.

Pack sizes: 1 or 10 vials of 5 ml.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

Block B, 204 Rivonia Road

Morningside

Sandton

2057

This leaflet was last revised in

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Registration numbers

SUGAMMADEX 200 DRL: 55/34/0852

SUGAMMADEX 500 DRL: 55/34/0853

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website:

<http://www.drreddys.co.za>

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

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